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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,722	12/28/2004	Tetsuo Asaki	44342.022000	5161

7590 10/06/2006
Greenberg Traurig
200 Park Avenue
New York, NY 10166

EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT PAPER NUMBER

1624

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/519,722

Applicant(s)

ASAKI ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/28/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendment, which included amendment to claims 4-8 and addition of new claims 9-11, filed on 12/28/2004, is made of record. Claims 1-11 are now pending.

Information Disclosure Statement

Reference cited in the Information Disclosure Statement, filed on 12/28/2004, is made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim and share the same indefiniteness.

1. Claim 1 is indefinite for more than one reason. The phrase "An amide derivative, which is a compound of ..." is vague and unclear. The definition of R¹ as a cyclic amino group is vague and unclear as to what is included or excluded. As recited it is not clear whether it is limited to secondary cyclic amines or includes tertiary, quaternary etc. The nature of the amine remains unknown. In addition, as recited it appears to be a cyclic ring containing one nitrogen. But the proviso at the end of A choices appears to include more than one nitrogen and other elements as well.

2. The exception at the end of A choice is also not clear. It is not clear whether the exception excludes some choices or includes some choices.

3. Claims 5-8 appear to be duplicates of claim 4 as there is no material difference between claim 4 and claims 5-8. Note the same active ingredient is used for the composition. Note there is no material difference between these claims and claim 4 as they rely on the same scope of active ingredient. Different intended use in such claims are given no material weight. Note *In re Tuominen* 213 USPQ 89.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmermann et al. 5,521,184.

Zimmermann et al. teaches several pyrimidine compounds and their composition for treating tumors. See formula I and note when R_1 is pyrazinyl or pyridyl, and the phenyl is substituted with formula II, with the given definition of R_{10} , compounds taught by Zimmermann et al., include instant compounds. See entire document. Especially, see examples 19 and 21.

Instant claims require a R^2 substituent in the phenyl ring.

Although Zimmermann et al. exemplifies few compounds, Zimmermann et al., teaches equivalency of exemplified compounds with those generically claimed. See formula I in column 1 and note R_{10} is permitted to be optionally substituted phenyl and heterocyclic ring (see column 2, lines 36-46). Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted pyrimidine compounds including various substituents in phenyl ring as permitted by the reference and expect resulting compounds (instant compounds) and their composition possess the uses taught by the art in view of the equivalency teaching outline above.

Furthermore, while the exemplified compound 21 do not anticipate the scope of instant claims in view of $R^2 = \text{alkyl}$, they are very closely related having

While said compound doesn't anticipate the scope of instant claims, they are very closely related, being compounds that differ in having H in the reference on phenyl ring vs. methyl in the instant. However, compounds that differ only by CH_3 Vs H are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Wood* 199 USPQ 137; *In re Lohr* 137 USPQ 548.

Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).


Venkataraman Balasubramanian

9/29/2006